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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,549	10/29/2001	Michael A. Bowen	D0034 NP	8020

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EXAMINER	
PROUTY, REBECCA E	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/005,549	BOWEN ET AL.	
	Examiner	Art Unit	
	Rebecca E. Prouty	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *6-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-18 are still at issue and are present for examination.

Applicants' arguments filed on 3/15/04, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claims 6-17 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the response filed 7/9/03.

Claims 1-5 and 18 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. The rejection is explained in the previous Office Action.

Applicants argue that the assertion that SEQ ID NO:2 encodes a ubiquitin conjugating enzyme is sufficient to satisfy the utility requirement of 35 U.S.C. 101. This is not persuasive because as discussed in the Utility guidelines issued by the PTO, an asserted utility must be specific, substantial and credible to satisfy the utility requirement of 35 U.S.C. 101. The assertion that SEQ ID NO:2 encodes a ubiquitin

conjugating enzyme does not meet the specific and substantial requirements as the assertion is not sufficiently specific that a skilled artisan would know what enzymatic reaction could be accomplished using the disclosed protein. Importantly the specification does not disclose to what ubiquitin could be conjugated. As previously discussed, ubiquitin conjugating enzymes comprise a highly diverse group of proteins which conjugate ubiquitin to a wide variety of different proteins with different enzymes having an enormous diversity in the specificity of substrates utilized (See for example Hershko et al). As ubiquitin conjugating enzymes are such a large diverse family of enzymes, a mere disclosure that a protein is a ubiquitin conjugating enzyme without a more specific recitation of what type of ubiquitin conjugating enzyme (i.e., what protein(s) is/are conjugated) is insufficient to provide a substantial utility as the skilled artisan would require further research to identify or reasonably confirm a real world context of use. Applicants argue that ubiquitin conjugating enzymes have known uses for "diagnosis, treatment or prevention of cancers and tumors, or immune, lymphoproliferative, or neurodegenerative disorders". However, these uses do not apply to all ubiquitin conjugating enzymes but only to individual

enzymes within this class. Neither the specification nor the prior art provide any information that links the use of the polypeptide of SEQ ID NO:2 or the polynucleotide of SEQ ID NO:1 and its variants to any specific disease state and it is just as likely that there is none. In view of the failure of the specification to provide a correlation of the claimed polynucleotide to a specific disease state and the necessary guidance for using the claimed polynucleotide to diagnose and/or treat a specific disorder, significant further research would be necessary for the skilled artisan to use the claimed polynucleotides in a real world context, and thus the asserted utility is not substantial.

Even if applicants provide evidence that polynucleotides encoding SEQ ID NO:2 have a specific, substantial and credible utility under 35 U.S.C. 101, the following rejection applies.

Claims 1-5 and 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides encoding SEQ ID NO:2, does not reasonably provide enablement for any polynucleotide encoding any ubiquitin conjugating enzyme having at least 80% identity to SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected,

to make the invention commensurate in scope with these claims. The rejection is explained in the previous Office Action.

Applicants appear to believe that amendments to the claims to limit the claims to polynucleotides encoding ubiquitin conjugating enzymes having at least 80% identity to SEQ ID NO:2 overcomes the instant rejection. However, this is not the case as the instant claims remain not commensurate in scope with the enabling disclosure for the same reasons presented in the previous Office Action.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Specht et al. (WO99/46375). A copy of a machine-translation of Specht et al. is included in the instant Office Action for applicants benefit.

Applicants appear to believe that amendments to the claims to limit the claims to polynucleotides encoding ubiquitin conjugating enzymes having at least 80% identity to SEQ ID NO:2 overcomes the instant rejection. However, page 102 of Specht et

al. teach that the polynucleotide of SEQ ID NO:217 of Specht et al. encodes the polypeptide of SEQ ID NO:248 which is shown on page 222 of Specht et al. Residues 8-378 of SEQ ID NO:248 of Specht et al. are identical to residues 53-422 of SEQ ID NO:2 of the instant application. Thus SEQ ID NO:248 of Specht et al. is 88% identical to the full length of SEQ ID NO:2 of the instant application (i.e., 370 residues identical/422 possible x 100%). Furthermore, as SEQ ID NO:248 of Specht et al. includes all of the catalytic domain (i.e., residues 248-411) of SEQ ID NO:2, SEQ ID NO:248 of Specht et al. is a ubiquitin conjugating enzyme and SEQ ID NO:217 of Specht et al. which encodes this protein anticipates the instant claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that

was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Specht et al. (WO 99/46375). The rejection is explained in the previous Office Action.

Applicant has not presented any arguments specifically traversing this rejection but instead relies upon the traversal discussed above. Therefore, this rejection is maintained for the reasons presented above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (571) 272-0937. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Rebecca Prouty
Primary Examiner
Art Unit 1652